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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,361	07/18/2000	Ambikaipakan Balasubramanium	UOC/136R	8955

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/618,361	Applicant(s) BALASUBRAMANIUM ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,12-15 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,12-15 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Please update the continuation data of this application at page 1 of the specification.

2. Amino acid sequences of human neuropeptide Y (NPY) (at page 7), and Exemplary compounds 39, 41, 42 and 43 (at page 38) are shown in the specification and required to have "SEQ ID NO:" in the sequence listing. Applicants must comply with the requirements of the sequence rules (37 CFR 1.81-1.825) and provide a copy of sequence listing and CRF containing all the sequences.

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. At page 58, there is "Background of the Invention", which is not an abstract.

4. Bracketing or underlining are commonly used to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii) and are normally not intended to be printed in the published patent. In claim 1, applicant has used "[where R is selected from the group consisting of hydrogen, alkyl, aryl, aralkyl, or alkylaryl]" and [where R is hydrogen or a lipophilic group, e.g., myristoyl, cholesteryl, t.Bu, etc.] in such a manner that appears that the instant brackets would indicate deleted material and is thus, confusing as to whether the amino acids in claim 1 would include the explanation for the R group or not. The applicant can only amend by cancellation and presentation of a new claim. See also changes to 37 CFR 1.121 in Amendment rules package (Final Rule published on 8 Sep. 2000 (65 Fed. Reg. 54603), see also O. G. of 19 Sep. 2000 (1238 Off. Gaz. Pat. Office 77)).

Election/Restrictions

5. Applicant's election without traverse of Group I, claims 1, 2, 12-15, 18-24 and N-α-Ac-Trp-Arg-Tyr-NH_2 in Paper No. 3 is acknowledged.

Claim objection

6. Claim 1 is objected to because of the use of the term "t.Bu". Deletion of "t.Bu" and use of "*t*-Bu" is suggested since *t*-Bu is a commonly used abbreviation for tertiary-butyl group.

7. Claim 21 is objected to because of the use of the term "being is". Appropriate correction is required.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 2 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 3 of U.S. Patent 6,235,718. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2 and 13-15 in the instant application disclose a compound having the formula of (R1)A1(R2)-A2-A3-W or a pharmaceutical acceptable salt, wherein each bond between two amino acids is a peptide bond or a pseudopeptide bond, or a tripeptide cited in

claim 2. This is obvious in view of claims 1, 2 and 3 in the patent which disclose a compound having the formula of (R1)A1(R2)-A2-A3-W, wherein each bond between two amino acids is a peptide bond or a pseudopeptide bond, a tripeptide cited in claim 2, or a pharmaceutical acceptable salt. Both sets of claims contain tripeptides having the formula of (R1)A1(R2)-A2-A3-W. Thus, claims 1, 2 and 13-15 in present application and claims 1, 2 and 3 in the patent are obvious variations of tripeptides having the formula of (R1)A1(R2)-A2-A3-W and are neuropeptide Y receptor antagonists or agonists.

9. Claims 12 and 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,235,718 in view of Domen *et al.* (WO 91/03494), Spindel *et al.* (U. S. Patent 5,410,018) or Sakurada *et al.* (U. S. Patent 5,993,843). Claims 1-3 in the patent disclose a compound having the formula of (R1)A1(R2)-A2-A3-W. Claim 12 in the instant application discloses a compound having the formula of (R1)A1(R2)-A2-A3-W is conjugated to a carrier of cationized albumin or polylysine. It would be obvious that claim 12 of the instant application contains the same compound as claims 1-3 of the patent in conjunction with the protein carrier, cationized albumin conjugated to an antigen peptide as taught by Domen *et al.* (page 5, lines 29-33; Example VI). Claims 18-22 and 24 in the instant application recite a therapeutic composition comprising the compound of claim 1 with a pharmaceutically acceptable carrier substance, the claims would obviously have contained the same composition as the patented claims in view of a therapeutic composition comprising a therapeutically effective amount of peptide with a pharmaceutically acceptable carrier substance such as magnesium carbonate in a form of a pill, tablet, capsule or liquid, for intravenous, subcutaneous or nasal administration to a subject in need of the compound as taught

by Spindel *et al.* (column 2, lines 33-41). Claim 23 in the instant application recites a therapeutic composition of claim 18 in a form of a biodegradable sustained release composition would have contained the same composition as the patented claims in view of a biodegradable sustained release preparation containing the active ingredient as taught by Sakurada *et al.* (column 3 lines 50-column 4, line 4). Please note that intended use generally does not alter biological activity. Therefore, it is not usually patentably distinct in view of routes of administration and formulations. Patentability is based on the active ingredient for the most part unless the admixture has special properties, which later biological action of active ingredient.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 12-15 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "e. g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 1, 12-15 and 18-24 are indefinite because of the use of the terms "Dap", "Pyr" and "Tip". The terms "Dap", "Pyr" and "Tip" render the claim indefinite, it is not clear what the term means since these terms have not been explained in the specification. The full chemical name should be indicated at the first occurrence. Claims 1, 12-15 and 18-24 are also indefinite because of the use of the terms "Trp derivative", "etc." and "amino acid derivatives". The terms

"Trp derivative", "etc." and "amino acid derivatives" render the claim indefinite, it is not clear what compounds are intended as compared to the parent compound, Trp or an amino acid, and what else is in the R group of Tyr(R) regarding "etc.". Claims 12-15 and 18-24 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

11. Claim 2 is indefinite because it contains non-elected peptides.

12. Claim 18 is indefinite because of the use of the terms "capable of" and "NPY". The terms "capable of" and "NPY" render the claim indefinite, it is not clear to what extent the therapeutic composition controls an NPY mediated physiological response, and what the term "NPY" means. The full spelled out word should precede the term. Claim 18 is also indefinite because it contains non-elected inventions. Claims 19-24 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

13. Claims 19-24 are indefinite because of the use of the term "to a subject in need of said compound". The term "to a subject in need of said compound" renders the claim indefinite, it is not clear what a subject is, and under what condition the subject needs the compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Koenig *et al.* (EP 288965 (November, 1988)).

Koenig *et al.* teach a peptide having formula of L-B-A, wherein L is lipophilic residue, B is basic residue, A is aromatic residue and C-terminal carboxyl group is protected as an ester or amide, is useful as Phospholipase A2 inhibitor. For example, Z-Trp-Lys-Tyr-OMe (compound no. 2, page 4), Z-Trp-Lys-Tyr-NH_2 (compound no. 3), Ac-Trp-Lys-Trp-NH-$(CH_2)_4CH_3$ (compound no. 14), Z-Trp-Lys-Tyr-benzylamide (compound no. 40), Z-Trp-Lys-Tyr-phenethylamide (compound no. 41), Z-Trp-Lys-Tic-NH_2 (compound no. 43), are included in claim 1 of the instant application, thus meets the criteria of claim 1.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

Christopher S. F. Low
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December 26, 2001